TRANSDERM IQ- transderm iq patch
TRANSDERM IQ- transderm iq ointment
DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Transderm IQ

Active ingredients:

Lidocaine HCL 4%

Menthol 4%

Purpose:

Topical Anesthetic

Uses:

For the temporary relief of pain

Warnings:

For external use

Do not use:

More than 1 patch on your body at a time or on cut, iritated or swollen skin.
On puncture wounds
For more than 1 week without consulting a doctor

When using this product:

Use only as directed. Read and follow all directions and warnings on this label.
Rare cases of serious burns have been reported with products of this type.
Do not apply to wounds or damaged, broken or irritated skin.
Do not allow contact with the eyes and mucous membranes.
Do not bandage tightly or apply local heat (such as heating pads) to the area of use.
Do not use at the same time as other topical analgesics.
Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if:

Condition worsens
Redness is present
Irritation developes
Symptoms persist for more than 7 days or clear up and occur again within a few days.
You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children over 12 years:

Clean and dry the affected area.
Open pouch and remove one patch.
Remove the protective film from the patch and apply patch to the affected area.
Reseal pouch containing unused patches after each use.
Use 1 patch for up to 12 hours.

Children 12 years or younger:

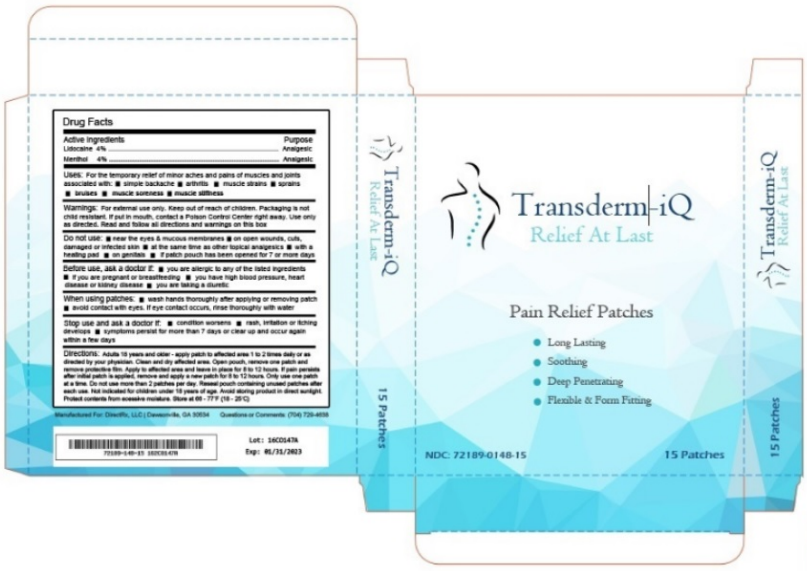
Ask a doctor

Other Information:

Avoid storing product in direct sunlight
Protect product from excessive mositure

Other Ingredients:

Acrylic Adhesive



DRUG FACTS LABEL

Drug Facts

Active Ingredients	Purpose
Lidocaine 4%	Analgesic
Menthol 4%	Analgesic

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ muscle strains ■ sprains ■ bruises ■ muscle soreness ■ muscle stiffness

Warnings: For external use only. Keep out of reach of children. Packaging is not child resistant. If put in mouth, contact a Poison Control Center right away. Use only as directed. Read and follow all directions and warnings on this box

Do not use: ■ near the eyes & mucous membranes ■ on open wounds, cuts, damaged or infected skin ■ at the same time as other topical analgesics ■ with a heating pad ■ on genitals ■ if patch pouch has been opened for 7 or more days

Before use, ask a doctor if: ■ you are allergic to any of the listed ingredients ■ if you are pregnant or breastfeeding ■ you have high blood pressure, heart disease or kidney disease ■ you are taking a diuretic

When using patches: ■ wash hands thoroughly after applying or removing patch ■ avoid contact with eyes. If eye contact occurs, rinse thoroughly with water

Stop use and ask a doctor if: ■ condition worsens ■ rash, irritation or itching develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days

Directions: Adults 18 years and older - apply patch to affected area 1 to 2 times daily or as directed by your physician. Clean and dry affected area. Open pouch, remove one patch and remove protective film. Apply to affected area and leave in place for 8 to 12 hours. If pain persists after initial patch is applied, remove and apply a new patch for 8 to 12 hours. Only use one patch at a time. Do not use more than 2 patches per day. Reseal pouch containing unused patches after each use. Not indicated for children under 18 years of age. Avoid storing product in direct sunlight. Protect contents from ecessive moisture. Store at 66 - 77°F (18 - 25°C)

TRANSDERM IQ

transderm iq patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72189-148(NDC:70512-013)
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	40 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ACRYLIC ACID (UNII: J94PBK7X8S)	

Product Characteristics			
Color		**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72189-148-15	15 in 1 BOX	04/07/2021	
1		1 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/07/2021	

TRANSDERM IQ

transderm iq ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72189-166
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-166-04	1 g in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/04/2021	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(72189-148) , manufacture(72189-166)

Revised: 6/2021 DIRECT RX